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# Study to identify novel drivers of platelet production in platelet apheresis donors

**Submission date**
20/06/2014

**Recruitment status**
No longer recruiting

**Registration date**
08/07/2014

**Overall study status**
Completed

**Last Edited**
15/10/2020

**Condition category**
Haematological Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
When people donate their blood platelets, they lose about 50% of them. Although this is perfectly safe, it is not clear how quickly their platelet count returns to normal and what causes this to happen: its possible that new platelets come from a reserve pool in the spleen and/or they are made by bone marrow. It is also not known what chemicals (growth factors) in the blood stream are important in making sure the number of platelets return to normal after donation. Knowing what these platelet growth factors are would be extremely useful for the treatment of patients with low platelet counts or in making platelets in the laboratory for transfusion. This study compares how quickly the number of platelets return to normal and what growth factors are present in regular donors verses people who are about to donate for the first time.

Who can participate?
Adult male platelet donors who regularly donate at the Cambridge Blood Centre and those that are due to donate for the first time.

What does the study involve?
A blood sample is taken from each participant 30 minutes before the platelet donation begins, in the opposite arm to which the donation is taken from. Another sample is taken 10 minutes after the donation is complete, one 4-8 hours after donation and then a number of additional samples on days 1,3,7 and 14 after the donation are taken. Donors are given the choice whether they would like the bloods to be done at home, place of work or at the Blood Centre.

What are the possible benefits and risks of participating?
There are no significant benefits or risks to taking part in this study. Donations take around 40 minutes longer than a normal platelet donation. The blood sampling may cause some mild discomfort and sometimes a small bruise.

When is the study starting and how long is it expected to run for?
September 2014 to September 2015

Who is funding the study?
NHS Blood and Transplant Trust Fund (UK)

Who is the main contact?
Cedric Ghevaert
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Cedric Ghevaert

### Contact details
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# Additional identifiers

### Protocol serial number
V2.0

# Study information

### Scientific Title
Reticulated platelet release and mass spectrometry analysis of plasma proteins after apheresis platelet donation by established and new donors

### Study objectives
Platelet donors donate their platelets through a process called apheresis. The donors have a cannula inserted into a vein and this blood line goes into a machine that spins the blood from the donor so as to separate it into different constituents (plasma, red cells, platelets). The red cells and plasma are given back to the donors, whilst the platelets are collected into a bag that can be transfused to a patient. The donation process takes about 1.5 hours. Platelet donors lose about 50% of their platelets, which gradually recover over 2 weeks with the formation of new platelets in the donors bone marrow. The hypothesis is that this is driven by growth factors (in addition to thrombopoietin). This study aims to identify the exact dynamics of platelet recovery following platelet donation and correlate it to the presence of plasma-bound growth factors through mass spectrometry

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
NRES Committee East of England  Cambridge South, 22/05/2014, ref: 14/EE/0194

### Study design
1-year laboratory study

### Primary study design
Observational

### Study type(s)
Other

### Health condition(s) or problem(s) studied
Platelet recovery following donation

### Interventions
The donors will have bloods taken pre and post donation and at another four timepoints over the next 2 weeks.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome(s)
The primary objective of this study will be the accurate measurement of the platelet count, the platelet volume and the quantity of newly formed platelets in platelet apheresis donors at the time of donation and at early (4-8 hours) and late (day 1, 3, 7 and 14) time points after donation. From the same blood sample used to look at the platelet count, the plasma will be isolated and analysed by mass spectrometry to identify which proteins contained in the blood promote new platelets release from the bone marrow.

### Key secondary outcome(s))
Platelet donors give a donation every 4 weeks. Samples will be taken from established platelet donors and from newly recruited donors to establish whether the platelet count recovery and plasma proteins are different when platelet donations are done frequently.

### Completion date
08/09/2015

## Eligibility

### Key inclusion criteria
Male platelet donors aged over 18 who are able to donate on Monday or Tuesday morning

### Participant type(s)
Healthy volunteer

**Healthy volunteers allowed**
No

**Age group**
Adult

**Lower age limit**
18 years

**Sex**
Male

**Key exclusion criteria**
1. Female donors
2. HPA-1a-5b negative donors who are used to maintain the supply of platelets for treatment of neonatal alloimmune thrombocytopenia

**Date of first enrolment**
08/09/2014

**Date of final enrolment**
08/09/2015

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**NHS Blood and Transplant**
Cambridge
United Kingdom
CB2 0PT

# Sponsor information

**Organisation**
NHS Blood and Transplant Trust Fund (UK)

**ROR**
https://ror.org/0227qpa16

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
NHS Blood and Transplant

**Alternative Name(s)**
National Health Service Blood and Transplant, UK National Health Service Blood and Transplant, NHSBT

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Local government

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |